Assembly Bill No. 34

CHAPTER 516

An act to add and repeal Article 8 (commencing with Section 1627) of Chapter 4 of Division 2 of the Health and Safety Code, relating to umbilical cord blood banking.

[Approved by Governor October 11, 2007. Filed with Secretary of State October 11, 2007.]

LEGISLATIVE COUNSEL'S DIGEST

AB 34, Portantino. Umbilical Cord Blood Collection Program.

Existing law, administered by the State Department of Public Health, contains provisions governing the licensure of blood banks, including provisions relating to licensure for purposes of umbilical cord blood banking storage services. Existing law also requires the department to conduct the Umbilical Cord Blood Community Awareness Campaign.

This bill would require the department to establish, by January 1, 2010, and until January 1, 2015, the Umbilical Cord Blood Collection Program for the purpose of increasing the amount of umbilical cord blood that is donated in the state and that will be added to the national inventory. The bill would authorize the department, to the extent private or public funds are identified for this purpose, to contract with blood banks that are licensed or accredited to provide umbilical cord blood banking storage services, for the purpose of collecting and storing umbilical cord blood.

The bill would require that any funds available for purposes of the program be deposited into the Umbilical Cord Blood Collection Program Fund, which this bill would create. The bill would require that the moneys in the fund be available for expenditure, upon appropriation by the Legislature, for that purpose. The bill would also require that information collected pursuant to the program be confidential, and be used solely for the purposes of the program, as prescribed.

The bill would provide that its provisions shall only become operative if SB 962 of the 2007–08 Regular Session is enacted and becomes operative.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

- (a) (1) The blood left in the umbilical cord after a baby has been delivered is a rich source of stem cells known as Hematopoietic progenitor cells (HPCs) that can be used for transplants for over 70 conditions. These disorders and diseases include all of the following:
 - (A) Blood cancers such as leukemia, myeloma, and lymphoma.

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(B) Immunodeficiencies and genetic diseases, including sickle cell anemia, thalassemia, inherited marrow failure disorders.

- (C) Inherited disorders or errors of metabolisms.
- (2) Research is underway to study how HPCs can be applied to additional conditions. While stem cells from bone marrow have typically been used for stem cell transplants, umbilical cord blood stem cells have significant advantages over bone marrow.
- (b) Umbilical cord blood is typically discarded after a birth. In the last two decades, since determining the viability of using this blood as a source for stem cell transplants, umbilical cord blood began to be banked for future use. Major authorities on the subject, including the Institute of Medicine of the National Academies, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists, have stated that the most effective use of umbilical cord blood is to publicly bank this blood so that it can be entered in a national registry, such as the National Marrow Donor Program, to be available for anyone in need.
- (c) Efforts are already under way to increase our national inventory. As of 2007, over 50,000 usable units of umbilical cord blood are in registered inventories. The Institute of Medicine of the National Academies published a roadmap in 2005 to building the inventory, "Cord Blood Establishing a National Hematopoietic Stem Cell Bank Program" calling for an increase in both the size and the genetic diversity of our inventory. If the inventory is genetically diverse, based on racial and ethnic backgrounds, an inventory with as few as 300,000 units could match almost all in need. With more than 550,000 births a year in California, 300,000 units should not be an insurmountable goal.
- (d) Federal legislation (H.R. 2520 2005) was enacted to support these efforts. Grants were authorized to six entities, including one bank in California, to build the national inventory with a goal of obtaining an additional 150,000 units. It is the intent of this Legislature to enhance national efforts by adding an increased number of units from California. The more the inventory mirrors the genetic makeup of our state's population, the greater the chance our citizens will find a match when they are in need. Every year tens of thousands of Californians needlessly suffer and die from lack of stem cell transplants due to failure to obtain a tissue match.
- (e) The greatest challenge is not a lack of potential supply of umbilical cord blood, but rather determining which blood is needed to diversify the inventory and how to target those populations. In 2006, the Institute of Medicine cited a cost of \$1,500 to collect, test, and store each unit, and of \$500 per collected, but ultimately discarded, unit. Discarded units can be used for research on other potential uses. Collections must be strategic and selective, as there is limited banking capacity, and not everyone who wants to donate will be able to donate.
- (f) As part of each contract or grant, the bank shall demonstrate plans to target populations for education and awareness about public banking of umbilical cord blood.

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SEC. 2. Article 8 (commencing with Section 1627) is added to Chapter 4 of Division 2 of the Health and Safety Code, to read:

Article 8. Umbilical Cord Blood Program

- 1627. (a) On or before January 1, 2010, the State Department of Public Health shall establish the Umbilical Cord Blood Collection Program for the purpose of increasing the inventory of umbilical cord blood donated from Californians which will be part of the national umbilical cord blood inventory. Units collected shall be entered into a national registry and made available to the public for purposes of human stem cell transplant. Units collected but unusable for transplant may be made available for research to further the understanding of the use of umbilical cord blood as tissue to treat human diseases.
- (b) When umbilical cord blood is used for research, research protocols shall be approved by the Committee for the Protection of Human Subjects or an institutional review board, as defined in subdivision (e) of Section 125330.
- (c) All blood collected for either transplant or research shall follow all applicable law and guidelines applicable to donor confidentiality and security of donor information. All information collected shall be confidential and shall be used solely for the purposes of the program.
- 1628. (a) To the extent public or private funds or grants are identified and secured for these purposes, the Umbilical Cord Blood Collection Program may identify and provide funds for grants or contracts with qualified umbilical cord blood banks, licensed or accredited pursuant to Section 1604.6, for the purposes of collecting and storing genetically diverse umbilical cord blood for public transplantation purposes.
- (b) No state funds, unless specifically appropriated for this purpose, shall be used for implementation of this section. Any funds made available for purposes of this article shall be deposited into the Umbilical Cord Blood Collection Program Fund, which is hereby created in the General Fund. Moneys in the fund shall be available, upon appropriation by the Legislature, for purposes of this article. The fund shall include any federal, state, and private funds made available for purposes of the program, and, notwithstanding Section 16305.7 of the Government Code, any interest earned on moneys in the fund.
- 1629. In implementing the program, the department shall make every effort to avoid duplication or conflicts with existing and ongoing programs and to leverage existing resources.
- 1630. This article shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

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SEC. 3. This act shall only become operative if Senate Bill 962 of the 2007–08 Regular Session, is enacted and becomes operative.